

# 3 Year Follow-up Study

mia<sup>®</sup>  
FEMTECH



## 100 Breast Harmonizations\*

\*21 cases included consumers with a benign breast reconstruction indication, such as breast asymmetries and mild chest wall deformities.

## Consumer Follow-Up Compliance Rates:

1 year  
98%

2 year  
90%

3 year  
93%

## Average times:

### Infiltration



Administration of tumescent local anesthesia in the subglandular space.

6 mins

### Skin-to-Skin Procedure



Creation and confirmation of the pocket and implant placement.

11 mins

### Immediate Postoperative Phase



Time spent in recovery room.

42 mins

Time from the first incision to closure on the final breast 27 mins

## Average Return to Daily Activities:

2.8  
days

## Average Return to Exercise:

20.1  
days

## Three-year results from Mia<sup>®</sup> Femtech Clinical Study

### Mia FemTech<sup>®</sup> Kaplan Meier Risk of Key Complications Through Three Years

Primary Augmentation	1-year (N=100),95% CI	2-year (N=100),95% CI	3-year (N=100),95% CI
Capsular contracture (Baker Grade III/IV)	0.0%	0.0%	0.0%
Rupture, suspected or confirmed*	0.0%	0.0%	0.0%
Infection	0.0%	0.0%	0.0%
Seroma	0.0%	0.0%	0.0%
Hematoma	0.0%	0.0%	0.0%
Rippling	0.0%	0.0%	0.0%
Inferior malposition	0.0%	0.0%	0.0%
Malposition/Displacement**	1.0%	1.0%	1.0%
Changes in Nipple Sensation	0.0%	0.0%	0.0%
Changes in Breast Sensation	0.0%	0.0%	0.0%
Any reoperation	0.0%	0.0%	1%

\*Includes overall rupture rate and MRI cohort (33 participants/66 implants), combined.

\*\*Malposition: 1 patient had an implant malposition and underwent (L) implant reposition; no implant exchange.

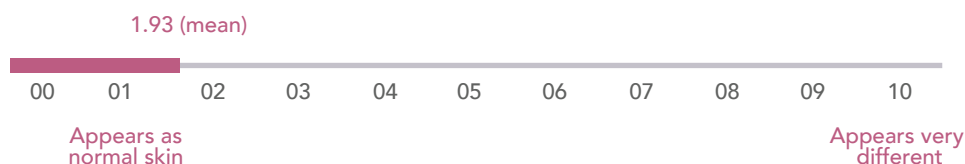


## MRI Sub Study:

- 33 consumers
- Between 18 to 21 months post procedure
- 0% Rupture, Gel Migration and Gel Fracture

## The Patient and Observer Scar Assessment Scale (POSAS)\*

### Consumer Opinion



\*The POSAS was administered to all study participants at scheduled follow-up visits (3, 6, 12, 24 and 36 months). POSAS is a validated tool used to assess scar quality. Reference: Establishment Labs, CLINR-001035. Fifth Progress Report for Minimally Invasive Breast Augmentation Traditional Feasibility Study (CLINP-001007). Data on File.